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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/735,561	12/12/2003	David James Dooley	PC 25627A	3925
28880	7590	01/08/2009		
PFIZER INC. PATENT DEPARTMENT, MS8260-1611 GROTON, CT 06340			EXAMINER ROYDS, LESLIE A	
			ART UNIT 1614	PAPER NUMBER
			NOTIFICATION DATE 01/08/2009	DELIVERY MODE ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

~IPGSGro@pfizer.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/735,561	<b>Applicant(s)</b> DOOLEY ET AL.	
	<b>Examiner</b> Leslie A. Royds	<b>Art Unit</b> 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 09 October 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 17-19 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 17-19 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

**Claims 17-19 are presented for examination.**

**A request for continued examination under 37 C.F.R. 1.114, including the fee set forth in 37 C.F.R. 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 C.F.R. 1.114, and the fee set forth in 37 C.F.R. 1.17(e) has been timely paid, the finality of the previous Office Action has been withdrawn pursuant to 37 C.F.R. 1.114. Applicant's payment and submission filed October 9, 2008 have been received and entered into the present application. Accordingly, prosecution has been reopened.**

**The present requirement for election of species is being applied during the course of prosecution of the instant application following consideration of Applicant's newly added claims 17-19, directed to the treatment of fibromyalgia with three distinctly different species of concomitant disorder.**

**Applicant is advised that the present requirement will direct further prosecution of the presently pending claims based upon Applicant's election of species to which prosecution on the merits will be restricted. Should Applicant's elected species be found allowable, examination will be expanded to other claimed species of concomitant disorder.**

#### ***Requirement for Election***

**This application contains claims directed to the following patentably distinct species of concomitant disorder occurring with fibromyalgia.**

**Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.**

**Regarding the instantly claimed species of concomitant disorder occurring with fibromyalgia, the species of disorder are unique and distinct from one another such that the patient populations treated via**

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each of the methods do not necessarily overlap in scope with any one or more of the other claimed inventions. The objective(s) as recited in the present claims for which the claimed composition must be therapeutically effective are each distinct from one another in etiology, pathophysiological manifestations, treatment protocol (i.e., duration of treatment, dosage amounts of active agent, frequency of treatment, etc.) and patient population such that a comprehensive search for the claimed compound in an amount effective to treat, for example, a patient with fibromyalgia and premenstrual dysphoric disorder, would not necessarily anticipate, suggest or render obvious the administration of the same or different compound in an amount effective to treatment an etiologically and pathophysiologically distinct disorder, such as fibromyalgia with concomitant major depressive disorder. Notwithstanding that Applicant may have established an underlying commonality to this genus of disorders, namely that each is treatable via the administration of the claimed compound, it remains that the art does not necessarily recognize such a shared characteristic as being common to the entire scope of conditions encompassed by the claims, nor does the art necessarily recognize each as amenable to the same type of pharmacologic therapy. Each is considered patentably distinct from the others because the patient populations, dosage amounts and therapeutic protocol for treating the claimed disorders are each unique to the type of disorder being treated such that a comprehensive search for the claimed compound in an amount effective for the treatment of a particular disorder (or combination of disorders) in the prior art would not necessarily encompass a comprehensive search of the patent or non-patent literature for the claimed compound in an amount effective for the treatment of any one or more other disorders (or combination of disorders). Furthermore, the species as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

Moreover, there is an examination and search burden for these patentably distinct species due to their mutually exclusive characteristics. The species require a different field of search (e.g., searching different classes/subclasses or electronic resources, or employing different search queries); and/or the

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prior art applicable to one species would not likely be applicable to another species; and/or the species are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

***Applicant's election must be made consistent with the following instructions:***

Applicant is required to elect a **single disclosed specie** of concomitant disorder from those specifically claimed in:

(i) instant claim 17, directed to premenstrual dysphoric disorder as the concomitant disorder;

(ii) instant claim 18, directed to dysthymia as the concomitant disorder; or

(iii) instant claim 19, directed to major depressive disorder as the concomitant disorder.

Applicant is cautioned that the election of a particular specie of disorder, wherein the elected specie is/are not adequately supported by the accompanying specification, may raise an issue of new matter under the written description requirement of 35 U.S.C. 112, first paragraph.

**Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species to be examined consistent with the instructions *supra* even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected species**, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, Applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, Applicant must indicate which are readable upon the elected species. Please reference MPEP §809.02(a).

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species to be examined even though this requirement be traversed (37 C.F.R. 1.143) and (ii) an identification of the claims encompassing the elected species.

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The election of species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the election of species requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, Applicant must indicate which of these claims are readable on the elected species.

Should Applicant traverse on the ground that the inventions or species are not patentably distinct, Applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the Examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie A. Royds whose telephone number is (571)-272-6096. The examiner can normally be reached on Monday-Friday (9:00 AM-5:30 PM).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on (571)-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Leslie A. Royds/  
Patent Examiner, Art Unit 1614

December 23, 2008

/Ardin Marschel/  
Supervisory Patent Examiner, Art Unit 1614